UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

LAURI BELL, *et al*,	§	
	§	
Plaintiffs,	§	
VS.	§	CIVIL ACTION NO. 4:20-CV-3678
	§	
ETHICON INC, *et al*,	§	
	§	
Defendants.	§	

MEMORANDUM & ORDER

Pending before the Court are Defendants Ethicon, Inc., Ethicon, LLC, and Johnson & Johnson's (collectively referred to as "Ethicon") Motion for Partial Summary Judgment and *Daubert* Motion to Limit or Exclude Case-Specific Testimony and Opinions of Bruce Rosenzweig, M.D. ("Dr. Rosenzweig"). (Docs. 42-44). After considering the Motions, the parties' briefs, and all applicable law, the Court determines that Ethicon's Motion for Partial Summary Judgment should be **GRANTED IN PART** and **DENIED IN PART** and its *Daubert* Motion should be **GRANTED IN PART** and **DENIED IN PART**.

I. BACKGROUND

Plaintiff Lauri Bell is one of the tens of thousands of individuals who have filed suit against Ethicon for injuries after treatment with Ethicon's pelvic mesh devices. Her spouse, Terrill Bell, is also a Plaintiff in this case.[1] Plaintiff Lauri Bell is a Texas resident who underwent surgery on December 10, 2009, at Memorial Hermann – Memorial City Hospital in Houston, Texas. (Doc. 1 ¶¶ 4, 10-11). This surgery was intended to treat her prolapse, stress urinary incontinence, and related symptoms. (Doc. 44-2 at 6). She was implanted with two Ethicon devices: TVT-O ("TVT")

[1] The Court refers to both Plaintiffs as the plural, "Plaintiffs." Any references to a single "Plaintiff" refer only to Lauri Bell.

and Prolift +M ("Prolift") by Dr. Christina Pramudji. (Doc. 1 at ¶¶ 9, 12). Since that surgery, Plaintiff has suffered a varied and chronic set of symptoms that she alleges were caused by the Ethicon devices.

Plaintiffs filed the present suit in March 2013. (Doc. 1). Plaintiffs' claims were consolidated into the Ethicon MDL, one of seven other pelvic mesh implant MDLs and over 100,000 cases adjudicated by Judge Joseph R. Goodwin in the Southern District of West Virginia. The case was adjudicated as part of the Ethicon MDL's Wave 10. (Doc. 18). In October 2020, the MDL court remanded Plaintiffs' case to this Court. (Doc. 57). Upon remand, the aforementioned motions were ripe for this Court's review.

II. MOTION FOR PARTIAL SUMMARY JUDGMENT

Ethicon seeks summary judgment on various claims brought by Plaintiffs. As to Plaintiffs' claims of Strict Liability – Defective Product (Count IV) and Fraudulent Concealment (Count VII), Plaintiffs accept the MDL court's prior rulings that those claims are not recognized by Texas law. As to the claims of Strict Liability – Manufacturing Defect (Count II), Constructive Fraud (VIII), Breach of Express Warranty (Count XI), Breach of Implied Warranty (Count XII), and Unjust Enrichment (Count XV), Plaintiffs state they no longer bring such claims. As a result, the remaining disputes for summary judgment pertain to Plaintiffs' claims of Strict Liability – Failure to Warn (Count III) and Negligent Infliction of Emotional Distress (Count X).

A. Legal Standard

Summary judgment is proper when there is no genuine dispute as to any material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). "A genuine issue of material fact exists if a reasonable jury could enter a verdict for the non-moving party." *Springboards to Edu., Inc. v. Houston Indep. Sch. Dist.*, 912 F.3d 805, 811 (5th Cir. 2019) (citation

omitted). The court can consider any evidence in "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). The moving party bears the burden of demonstrating the absence of a genuine issue of material fact. *Id.* at 325. Once a movant meets this burden, the burden shifts to the nonmovant to show the existence of a genuine fact issue for trial. *Id.* at 324. In deciding a summary judgment motion, the court must draw all reasonable inferences in the light most favorable to the nonmoving party, and it cannot make credibility determinations or weigh the evidence. *Buckingham v. Booz Allen Hamilton, Inc.*, 64 F. Supp. 3d 981, 984 (S.D. Tex. 2014) (citing *Reeves v. Sanderson Plumbing Products, Inc.*, 530 U.S. 133, 150 (2000)).

B. Choice of Law

The MDL court previously decided that the choice of law that applies is the place where the plaintiff was implanted with the product. *See, e.g.*, *Belanger v. Ethicon, Inc.*, No. 2:13-cv-12036, 2014 WL 346717, at *7 (S.D.W. Va. Jan. 30, 2014). Based on Texas law's most significant relationship test, the MDL court has determined that Texas law governs where the implant and alleged injuries occurred in Texas. *Lewis v. Ethicon, Inc.*, 2014 WL 186869, at *2 (S.D.W. Va. Jan. 15, 2014). Because Plaintiff's surgery and alleged injuries occurred in Texas, the Court will apply Texas law.

C. Analysis

i. Strict Liability for Failure to Warn (Count III)

To recover for a failure to warn claim, a plaintiff must show that (1) the warning was defective, and (2) the failure to warn was a producing cause of the injury. *Ackermann v. Wyeth Pharm.*, 526 F.3d 203, 208 (5th Cir. 2008) (citing *Porterfield v. Ethicon*, 183 F.3d 464, 468 (5th Cir. 1999)). With respect to causation, a plaintiff must show that the alleged inadequacy of the

warning "caused her doctor to prescribe the drug [or product] for her." *Id.* (citation omitted). If "the physician was aware of the possible risks involved in the use of the product but decided to use it anyway, the adequacy of the warning is not a producing cause of the injury." *Id.* (citation omitted). But if the physician was not aware of the risk, the plaintiff must show that, but for the inadequate warning, the physician would not have used the product. *Id.*

As to the first element, "Texas law generally holds that the adequacy of a product's warning is a question of fact to be determined by the jury." *McNeil v. Wyeth*, 462 F.3d 364, 368 (5th Cir. 2006). Ethicon does not seek summary judgment on the first element, so the Court's analysis assumes Plaintiffs will be able to show at trial that the warning was inadequate.

Ethicon argues Plaintiffs cannot prove causation because her implanting surgeon, Dr. Christina Pramudji, did not rely on the allegedly inadequate product warnings. At her deposition, Dr. Pramudji was asked if she relied on the Instructions for Use ("IFU") that came with the TVT and Prolift devices "to teach you how to perform the surgery," "use the product," or "educate you on the risks of the product." (Doc. 42-1 at 29:15-17, 31:3-14). Dr. Pramudji answered, "[n]o," she did not. *Id.* at 29:17, 31:14. Her testimony was that she learned about the risks of the devices through her training in medical school residency, discussions with her colleagues, and literature she read. *Id.* at 28:21-29:9.

But, Dr. Pramudji also testified that she had read the IFU for the two products at issue and had been familiar with them. (Doc. 52-1 at 109:18-20; 113:5-114:6). She was also asked if she had read the IFUs prior to implanting the devices in Plaintiff. (Doc. 42-1 at 109:21-22). Dr. Pramudji responded, "I don't remember if I did or not, because I had learned, you know, everything from my . . . ." *Id.* at 109:23-24. Unfortunately, neither party presents the remainder of her response.

But suffice it to note, she could not conclusively say whether she had read the IFU prior to deciding to implant the devices in Plaintiff.

Ethicon cites to *Lewis v. Johnson & Johnson*, in which the Fourth Circuit affirmed the MDL court's grant of summary judgment in another case. 601 F. App'x 205, 208 (4th Cir. 2015) (per curiam) (applying Texas law). There, the treating physician testified that she had read the IFU during her surgical fellowship in 2002, but had not read it again before prescribing the TVT to the plaintiff in 2009. *Id.* Additionally, when asked whether she relied on the instructions for use in prescribing the TVT, the physician answered she did not. *Id.* Based on that testimony, the Fourth Circuit held that "when a physician relies on her own experience and examination of a patient in deciding to prescribe a device, and not on the device's warning, the warning is not the cause of the patient's injury." *Id.*

The Fourth Circuit relied on two Fifth Circuit cases to reach its decision. *Id.* at 208-209. In *Pustejovsky v. PLIVA, Inc.*, the plaintiff had not shown causation because the physician did not recall ever reading the package insert. 623 F.3d 271, 277 (5th Cir. 2010). The court found that "[h]er lack of memory . . . does not preclude the possibility that she had read the materials, but neither can it sustain Pustevjosky's burden." *Id.* In *Porterfield v. Ethicon*, the surgeon testified he had "at no time prior to Porterfield's surgery" read Ethicon's IFU or any other Ethicon literature. 183 F.3d 464, 468 (5th Cir. 1999). He further testified that he was aware of the possible risks, but decided to use it anyway because the possible benefits outweighed the risks. *Id.*

The Fourth Circuit in *Lewis* rejected the plaintiff's attempt to distinguish these cases based on the fact that her treating physician *had* previously read the IFU, because the plaintiff "offer[ed] no evidence to rebut [the treating physician's] own testimony that she did not *rely* on the document in deciding to prescribe the TVT." *Lewis*, 601 F. App'x at 208 (emphasis in original).

This Court finds those cases distinguishable because Plaintiffs *have* offered evidence to rebut Ethicon's argument and evidence. First, the physician in *Lewis* definitively testified that she had not read the IFU in seven years, and that she had not read it before prescribing the TVT to the plaintiff. Dr. Pramudji, however, *could not remember* whether she had read the IFU before she implanted it in the present Plaintiff. Dr. Pramudji further testified that she had read the IFUs previously and was familiar with them. As described below, she was quite familiar with Ethicon's products.

Second, unlike the physicians in the authority discussed above, Dr. Pramudji had (or has, it is unclear whether that relationship exists today) been a preceptor with Ethicon since approximately 2004 or 2005. (Doc. 52-1 at 75:12-77:15). So within four years of Plaintiff's surgery, and likely less, Dr. Pramudji had been paid by Ethicon to lecture others about the products and train them on how to conduct the procedures. The key here is not that Ethicon paid Dr. Pramudji, though that is relevant later, but rather that Dr. Pramudji had a professional commitment to teach others about Ethicon products and therefore to be well-versed in the products. Dr. Pramudji's working relationship with Ethicon also placed her in a different position from the physicians who had never even read Ethicon's IFU and otherwise had no familiarity with the literature.

In sum, Dr. Pramudji's testimony creates ambiguity as to whether she had read the IFU before prescribing it to Plaintiff; and her preceptor relationship further adds to the notion that she would be familiar with Ethicon's literature. Viewing the evidence in light most favorable to Plaintiffs, Dr. Pramudji's testimony suggests that she is familiar with the IFU but she conducted independent research *in addition to* the IFU, "to educate [her] on the risks of the product." (Doc. 42-1 31:12-13). In other words, like any good physician, she did independent research but did not

solely rely on the IFU. This creates a genuine issue of material fact as to whether the inadequate warnings in the IFU were a producing cause of Plaintiff's injuries.

To illustrate further, the Court looks to a recent ruling in which the district court denied a similar, if not identical, argument by Ethicon. *See Johnson v. Ethicon, Inc.*, No. 20-CV-102-JPG, 2020 WL 3542872, at *5 (S.D. Ill. June 30, 2020) (denying summary judgment as to failure to warn claim). The district court found that, because the physician had read the IFU before, the IFU and "other information provided by Ethicon was part of the basis for his knowledge of the risks that he factored into his prescription decision." *Id.* "Thus, even if a long time ago, the IFUs and Ethicon's other warnings played a substantial, even if not exclusive, role in his understanding of the risks and benefits of the products." *Id.*[2]

The same is true here. Even if Dr. Pramudji did not exclusively rely on the IFUs to educate her on the risks, the evidence suggests she had been familiar with the IFUs and other literature from Ethicon. Thus, a genuine issue of material fact exists as to whether the IFUs played a role in her understanding of the risks. Along the same lines, a genuine issue of material fact exists as to whether Dr. Pramudji would have relied more heavily on the IFU, and would have reached a different risk-benefit conclusion, if the warnings had been adequate.

Yet a third reason this Court finds Ethicon's authority distinguishable is Dr. Pramudji's relationship with Ethicon. Summary judgment is not appropriate when "questions about the credibility of key witnesses loom . . . large and the evidence could permit the trier-of-fact to treat their testimony with skeptical scrutiny." *Deville v. Marcantel*, 567 F.3d 156, 165 (5th Cir. 2009) (internal quotations omitted and ellipses in original). "[A] motion for summary judgment cannot

[2] Although that court applied Illinois law, the reasoning applies equally.

be defeated solely by conclusional allegations that a witness lacks credibility," but "well-supported suspicion of mendacity may serve as a legitimate basis for the factfinder's reasonable inferences concerning the ultimate facts at issue." *Id.* (quoting *Thomas v. Great Atl. & Pac. Tea Co.*, 233 F.3d 326, 331 (5th Cir. 2000)).

Plaintiffs have provided evidence, beyond conclusory allegations, that Dr. Pramudji's relationship with Ethicon creates a "well-supported suspicion" of her credibility. Dr. Pramudji has admitted to having a relationship with Ethicon, including as an expert witness for Ethicon in this MDL. (Doc. 52-1 at 75:8-17). She was actively retained as an expert witness in the MDL, providing a report as recently as one month before her deposition as Plaintiff's treating physician. *Id.* at 79:5-8. She estimated having testified as an expert in this MDL a total of 20 to 40 times, and providing 70 to 80 expert reports. *Id.* at 80:16-81:12, 82:13-83:1. In every case in which she was either a fact or expert witness, she testified that the product was good and not responsible for the plaintiff's injuries. *Id.* at 98:18-99:1.

Dr. Pramudji has also been a paid preceptor for Ethicon's mesh products since approximately 2004 or 2005. *Id.* at 77:13-15. She would also receive pay to attend other meetings, associations, conventions, to promote Ethicon products. *Id.* at 78:11-16. Plaintiffs also point out that she was paid for her deposition testimony as a subpoenaed witness. Ethicon correctly responds that it is lawful to provide fees to a compelled witness. *See* 28 U.S.C. § 1821(a)(1). However, the compensation only further commingles her role as a treating physician and as an expert witness for Ethicon.

To be clear, the Court does not weigh the witness's credibility nor suggest she is dishonest. The Court finds only that Plaintiffs' evidence would allow a reasonable jury to treat her testimony with skepticism. Dr. Pramudji's relationship with Ethicon, in addition to being the implanting

physician, assures that her credibility will loom large at trial. It is also a salient distinction that was not present in Ethicon's cited authority. For these reasons, the Court **DENIES** Ethicon's Motion on the failure to warn claim.

ii. Negligent Infliction of Emotional Distress ("NIED") (Count X)

Ethicon correctly argues that Texas does not recognize a cause of action for NIED. Plaintiffs' only response is to insist that Plaintiff is entitled to damages for the mental anguish she suffered as a result of Ethicon's negligence. The Supreme Court of Texas has held that "that there is no general duty in Texas not to negligently inflict emotional distress" (also referred to as mental anguish). *Boyles v. Kerr*, 855 S.W.2d 593, 594 (Tex. 1993). Nonetheless, a plaintiff may still "recover mental anguish damages" if they were suffered "in connection with defendant's breach of some other legal duty." *Id.*; *see also SCI Texas Funeral Servs., Inc. v. Nelson*, 540 S.W.3d 539, 543 (Tex. 2018).

Plaintiffs continue to pursue independent tort claims of negligence, gross negligence, negligent misrepresentation, and similar claims sounding in fraud. However, Plaintiffs' own authority explains that mental anguish damages are not available in every tort case. *City of Tyler v. Likes*, 962 S.W.2d 489, 494-95 (Tex. 1997). But that is an issue for the damages phase and does not pertain to the current question of liability. At this stage, it is sufficient to conclude that Plaintiffs do not have an independent cause of action for NIED. Thus, Ethicon's motion for summary judgment as to Plaintiffs' claim for NIED (Count X) should be **GRANTED**, and that claim should be dismissed.

III. MOTION TO EXCLUDE CASE-SPECIFIC TESTIMONY OF BRUCE ROSENZWEIG, M.D.

Plaintiffs have retained Dr. Bruce Rosenzweig as a case-specific expert. Dr. Rosenzweig has also provided expert testimony on general issues in the Ethicon MDL and other pelvic mesh

MDLs. As described below, the MDL court has repeatedly found him qualified to testify on a number of topics. Here, Ethicon raises seven challenges to his expert testimony: (1) incorporating challenges to his general expert opinions; (2) as to safer alternative procedures; (3) "PVDF" as a safer alternative design; (4) as to his qualifications to testify on the adequacy of the warnings; (5) regarding the implanting physician's knowledge of the risks; (6) characteristics of TVT and Prolift; and (7) his prognosis of Plaintiff.

A. Legal Standard

Under Federal Rule of Evidence 702, an expert witness may testify if:

> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; (d) the expert has reliably applied the principles and methods to the facts of the case.

A court is charged with a "gatekeeping function" to ensure expert testimony is both reliable and relevant. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 597 (1993). The test for determining reliability is flexible and can adapt to the particular circumstances underlying the testimony at issue. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150-51 (1999).

B. Analysis

i. Incorporated challenge to Dr. Rosenzweig's general opinions

Ethicon begins by incorporating its challenges in its prior *Daubert* motions to exclude general opinions. This Court is under the impression that Ethicon refers to the general *Daubert* motions it has asked this Court to rule on, and that the parties will be providing a chart to assist the Court in adopting prior rulings. (*See* Minute Entry 03/10/2021). Therefore, this Court reserves ruling on those issues and will address them after the parties' future filing.

ii. Testimony on safer alternative procedures

Ethicon seeks to exclude Dr. Rosenzweig's testimony regarding safer alternative procedures. As a threshold issue, Ethicon admits that the MDL court had previously ruled that the safety of alternative procedures is a general causation issue; not one of specific causation. (Doc. 44 at 4 n.1). However, Ethicon argues that Dr. Rosenzweig's opinion here is case-specific because he will testify that "this Plaintiff would not have been injured had an alternative procedure been performed." *Id.* Plaintiffs respond that such opinions are general in nature and should be dealt with in the context of general causation motions.

The case has now been remanded to this Court, and Plaintiffs do not point to any ruling from the MDL court that would bind this Court under the law of the case doctrine. *See In re Ford Motor Co.*, 591 F.3d 406, 411-12 (5th Cir. 2009). At this stage, the Court believes it appropriate to rule on the issue.

Ethicon cites to the MDL court's prior ruling that it "agree[d] with Ethicon that alternative procedures/surgeries do not inform the issue of whether an alternative design for a product exists." *In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. MDL 2327, 2017 WL 1264620, at *3 (S.D.W. Va. Mar. 29, 2017) (excluding alternative procedures testimony for general causation expert). However, that ruling was rendered on an entirely separate *Daubert* motion for a general expert. *Id.* at *1. If we take Ethicon's position that this a case-specific issue, then this ruling is not as persuasive or binding as Ethicon would suggest.[3]

[3] The only other authority Ethicon cites to is a ruling on the meaning of an "alternative, feasible design" under Virginia and West Virginia law. *See Mullins v. Johnson & Johnson*, 236 F. Supp. 3d 940, 942 (S.D.W. Va. 2017). Because the meaning of an alternative, feasible design is a matter of state law—Texas law here—*Mullins* is inapposite.

A district court in Florida recently ruled against Ethicon on this identical argument, and found that, "Dr. Rosenzweig's opinion that alternate medical procedures were safe and effective . . . are relevant to demonstrating that the [product's] inherent risks outweigh its benefits." *Messina v. Ethicon, Inc.*, No. 6:20-cv-1170-Orl-40LRH, 2020 WL 7419586, at *4 (M.D. Fla. Dec. 17, 2020) (footnote omitted). The district court explained that Florida law applies the risk-utility test, which includes a determination of whether the benefits of the challenged design were outweighed by its risks. *Id.* Although the Court agreed that surgical procedures are not devices, such "surgical alternatives assist the jury in appreciating the risk-utility analysis." *Id.*

Upon review of Texas law on design defect claims, this Court agrees with *Messina*'s reasoning and finds it equally applicable here. For a design defect claim under Texas law, "a plaintiff must prove that (1) the product was defectively designed so as to render it unreasonably dangerous; (2) a safer alternative design existed; and (3) the defect was a producing cause of the injury for which the plaintiff seeks recovery." *Genie Indus., Inc. v. Matak*, 462 S.W.3d 1, 6 (Tex. 2015).[4] A "safer alternative design" is defined by statute, though the specific definition is not implicated in this discussion. *See* Tex. Civ. Prac. & Rem Code § 82.005(b).

But, "[a] safer alternative design is both a statutorily required element of a design defect claim and a factor considered when conducting a risk-utility analysis to determine whether a product is unreasonably dangerous." *Flock v. Scripto-Tokai Corp.*, 319 F.3d 231, 239 (5th Cir. 2003) (citations omitted). A product is "unreasonably dangerous" if its risks outweigh its utility, and is generally a question for the jury. *Id.* at 241 (citation omitted); *Genie*, 462 S.W. at 6. Texas'

[4] "[A] design-defect claim in Texas is governed by more than just the products-liability statute; it is a sort of hybrid between the statute and Texas common law." *Nester v. Textron, Inc.*, 888 F.3d 151, 156 n.1 (5th Cir. 2018) (citing *Hernandez v. Tokai Corp.*, 2 S.W.3d 251, 256 (Tex. 1999)).

risk-utility analysis has long required consideration of numerous factors. *See Flock*, 319 F.3d at 241. This analysis "does not operate in a vacuum, but rather in the context of the products' intended use and its intended users." *Timpte Indus., Inc. v. Gish*, 286 S.W.3d 306, 312 (Tex. 2009) (citation omitted).

Because Texas also applies a risk-utility analysis, the testimony on alternative surgical procedures is relevant and helpful to the jury as it informs whether the utility of the products at issue were outweighed by the risks in light of alternative treatments. Therefore, the Court **DENIES** Ethicon's Motion on this point and allows Dr. Rosenzweig's testimony on safer alternative procedures.

iii. Testimony regarding Dynamesh and "PVDF" polymer as an alternative design

Dr. Rosenzweig's report states that a sling made from polyvinylidene fluoride ("PVDF") or a "lightweight, large-pore polypropylene material," such as "Dynamesh," would have been a safer alternative to TVT and Prolift. (Doc. 44-2 at 22-23). Ethicon challenges this alternative design as unreliable and irrelevant. Ethicon contends that neither Dynamesh nor any other lightweight, large-pore polypropylene material was available at the time of Plaintiff's surgery, and thus Dr. Rosenzweig's testimony should be excluded.

Ethicon is correct that a safer alternative design must be "economically and technologically feasible" at the time in question. Tex. Civ. Prac. & Rem Code § 82.005(b). Ethicon cites many cases but none is binding nor persuasive. Indeed, Ethicon largely refers to dicta or completely inapposite circumstances. *See, e.g.*, *Dyer v. Danek Med., Inc.*, 115 F. Supp. 2d 732, 739 (N.D. Tex. 2000) (finding plaintiff failed to identify a safer design alternative altogether); *Brockert v. Wyeth Pharm., Inc.*, 287 S.W.3d 760, 770 (Tex. App. 2009) (holding a plaintiff cannot prove a safer alternative design by pointing to a substantially different product); *Militrano ex rel. Militrano v.*

Lederle Lab'ys., 769 N.Y.S.2d 839, 852 (Sup. Ct. 2003) (applying New York law to reject defectiveness through a product not approved by the FDA).

This Court did not find any authority in Texas, nor did Ethicon point to any, establishing that lack of FDA approval precludes an alternative design. In fact, the MDL court has repeatedly rejected Ethicon's argument and held that the fact that PVDF was not cleared by the FDA does not render the testimony unreliable nor does it have any bearing on whether PVDF mesh is a safer alternative to other mesh products. *See In re Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. MDL 2327, 2020 WL 1060970, at *3 (S.D.W. Va. Feb. 13, 2020) (citing its prior decisions); *Bellew v. Ethicon, Inc.*, No. 2:13-CV-22473, 2014 WL 12685965, at *6 (S.D.W. Va. Nov. 20, 2014) (allowing testimony regarding PVDF as alternative polymer). This Court agrees with the MDL court's reasoning and applies the same holding to the present Motion. Ethicon is free to cross-examine Dr. Rosenzweig at trial about these issues, but the Court **DENIES** its Motion and will allow the testimony.

iv. Testimony regarding adequacy of warnings in instructions for use

Ethicon argues that Dr. Rosenzweig's opinions about the products' IFU should be excluded because he is not qualified to opine about the adequacy of the warnings in the IFU. Plaintiffs respond that the MDL court already held Dr. Rosenzweig is qualified to testify about the inadequacy of product warnings in both the Ethicon and Boston Scientific MDL.

This appears to be a general issue—not case-specific. The "law of the case" doctrine binds this Court to adopt the MDL court's rulings on Dr. Rosenzweig's general expert opinions. *See In re Ford Motor Co.*, 591 F.3d 406, 411-12 (5th Cir. 2009). And here, Plaintiffs properly point this Court to prior rulings on this general issue. The MDL court previously ruled on Ethicon's *Daubert* motion to exclude Dr. Rosenzweig's general opinions, and found Dr. Rosenzweig is "qualified to

testify generally on the adequacy of the [] product warnings and marketing materials." *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 704 (S.D.W. Va. 2014).

But even if the prior ruling in *Huskey* did not control, the facts developed in that ruling about Dr. Rosenzweig show he is indeed qualified to testify about the adequacy of the IFUs. Ethicon posits that, although the MDL court found Dr. Rosenzweig qualified to offer warning opinions in 2014, "[t]he MDL court has since refined its earlier approach to this issue and held that an expert 'must possess additional expertise to offer expert testimony about what information should or should not be included in an IFU.'" (Doc. 53 at 3).

Ethicon is mistaken. Even in its *Huskey* decision, the MDL court applied the same principle that an expert must be qualified, not just as a urogynecologist, in order to testify about warnings. Under that standard, the MDL court found that Dr. Rosenzweig has consulted on product warnings in the past, has served on another company's scientific advisory committee that worked on similar documents, and has reviewed numerous IFU for mesh products. *Huskey*, 29 F. Supp. 3d at 704. In fact, Ethicon made a similar argument in *Huskey* by relying on a prior ruling that a Dr. Shull was not qualified to testify about product warnings. *Id.* at 704 n.2. The MDL court clarified that its holdings regarding Dr. Shull were inapposite to Dr. Rosenzweig because Dr. Shull had admitted he lacked the prior experience that Dr. Rosenzweig holds. *Id.* In other words, this is an expert-by-expert analysis. For that same reason, Ethicon's reliance on two 2016 rulings by the MDL court are inapposite to Dr. Rosenzweig's qualifications. *See In re Ethicon, Inc.*, No. 2:12-MD-02327, 2016 WL 4536885, at *2 (S.D.W. Va. Aug. 30, 2016) (holding Dr. Margolis did not possess additional expertise to testify about warnings in an IFU); *In re Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. MDL 2327, 2016 WL 4500767, at *4 (S.D.W. Va. Aug. 26, 2016) (same as to Dr. Blaivas).

In sum, the MDL court's prior rulings on Dr. Rosenzweig's experience shows he is qualified to testify about the IFU. The Court **DENIES** Ethicon's Motion on this point.

v. Testimony regarding implanting physician's knowledge about risks

Ethicon also seeks to exclude Dr. Rosenzweig's testimony about what Plaintiff's implanting physician, Dr. Pramudji, knew or did not know prior to Plaintiff's surgery. (*See* Doc. 44-2 at 24). This dispute harkens back to Ethicon's motion for partial summary judgment. However, the specifics of what Dr. Pramudji did or did not know at the time, discussed at length by Ethicon, are largely irrelevant here. The central inquiry is whether Dr. Rosenzweig's opinions regarding what Dr. Pramudji knew, are relevant, reliable, or helpful to the jury.

The Court agrees with Ethicon. The MDL court has at least on one occasion excluded "state-of-mind testimony" regarding what physicians know or should know about specific topics. *In re Ethicon, Inc.*, No. 2327, 2016 WL 4493457, at *3 (S.D.W. Va. Aug. 25, 2016). Dr. Rosenzweig's opinion does not appear to rely upon nor be based on his expertise. *See* Fed. R. Evid. 702. His opinion also does not seem to be grounded in personal perception or personal knowledge of the matter. *See* Fed. R. Evid. 701; Fed. R. Evid. 602. The Court does not find this testimony reliable for *Daubert* purposes nor generally admissible. Moreover, Dr. Pramudji has provided deposition testimony and would be available to testify herself as to what she knew or did not know at the time. For these reasons, the Court **GRANTS** Ethicon's Motion on this point and excludes Dr. Rosenzweig's testimony regarding what Dr. Pramudji knew or did not know at the time of Plaintiff's surgery.

vi. Testimony regarding problems with TVT and Prolift devices

Dr. Rosenzweig makes several statements in his case-specific expert report that Plaintiff's TVT and Prolift devices suffer from several problems, including: degradation, chronic foreign

body reactions, fibrotic bridging, contracture, shrinkage, fraying, particle loss, biofilm formation and infections, sharp edges, roping, curling, deformation, and collapsing. (Doc. 44-2 at 16, 23-25). Ethicon does not challenge Dr. Rosenzweig's opinion that the devices can *generally* suffer from such complications, but instead argues his opinions are speculative because there is no evidence that those problems existed in the *specific* devices that the surgeon implanted in Plaintiff. The issue is whether Dr. Rosenzweig provided a reliable differential diagnosis, ultimately concluding that her injuries were caused by such problems with the devices in Plaintiff's body.

A differential diagnosis is a method for a diagnosis "accomplished by determining the possible causes for the patient's symptoms and then eliminating each of these potential causes until reaching one that cannot be ruled out or determining which of those that cannot be excluded is the most likely." *Johnson v. Arkema, Inc.*, 685 F.3d 452, 468 (5th Cir. 2012) (quoting *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 262 (4th Cir. 1999)).[5] The method "typically, though not invariably, is performed after physical examinations, the taking of medical histories, and the review of clinical tests, including laboratory tests." *Id.* (internal quotations and citation omitted). In the Fifth Circuit, a differential diagnosis may be a reliable method under *Daubert*, but it is not reliable *per se*. *Sims v. Kia Motors of Am., Inc.*, 839 F.3d 393, 401 (5th Cir. 2016) (citations omitted). The district court has broad direction "to make the fact-specific inquiry in a given case." *Id.* at 402. But "while exercising its role as a gate-keeper, a trial court must take care not to transform a *Daubert* hearing into a trial on the merits." *Pipitone v. Biomatrix, Inc.*, 288 F.3d 239, 250 (5th Cir. 2002).

[5] The MDL court has used the same Fourth Circuit standard when discussing differential diagnoses. *See Huskey*, 29 F. Supp. 3d at 702; *Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501, 517 (S.D.W. Va. 2014).

The key principle is that an expert must both (1) "rule in" the challenged drug or product as a general cause for the injuries suffered, and (2) "rule out" alternative causes in the plaintiff's specific case. *Sims*, 839 F.3d at 401-402 (citing *Pipitone*, 288 F.3d at 248). Put differently, the expert cannot use the differential diagnosis to circumvent proving general causation. *Johnson*, 685 F.3d at 468.

As Ethicon points out, the MLD court previously rejected Dr. Rosenzweig's specific causation opinions on similar facts. *Huskey*, 29 F. Supp. 3d at 707-708. However, *Huskey* did not discuss the methodology of differential diagnosis with respect to his opinions, the methodology Dr. Rosenzweig uses here. *See id.*; (Doc. 44-2 at 16). Dr. Rosenzweig's general expert opinions include his view that the mesh used in the TVT and Prolift devices were not suitable for treating stress urinary incontinence because of degradation, reactions, fibrotic bridging, contracture, shrinking, fraying, particle loss, biofilm formation and infections, and other related deformations. (Doc. 44-2 at 16). Both parties admit that the MDL court already found Dr. Rosenzweig qualified to offer general causation opinions regarding these characteristics in Ethicon's products. *See Huskey*, 29 F. Supp. 3d at 707-708. Dr. Rosenzweig's experience as a pelvic floor surgeon and in surgeries dealing with such complications has been well-established in the pelvic mesh MDLs. *See, e.g., id.* at 707. Based on the evidence and prior rulings, the Court finds that Dr. Rosenzweig's differential diagnosis establishes a basis for "ruling in" the characteristics of Ethicon's mesh products as causes for the type of injuries Plaintiff allegedly suffered.

The next question is whether Dr. Rosenzweig "ruled out" other likely causes for Plaintiff's injuries. Dr. Rosenzweig did not physically examine[6] Plaintiff, nor did he have opportunity to

[6] The fact that Dr. Rosenzweig did not physically examine Plaintiff does not render his diagnosis unreliable. *See Tyree*, 54 F. Supp. 3d at 565.

examine her mesh implants. But he did review her medical records, including treating physicians' observations of her mesh implant. (Doc. 44-2 at 6-15). Upon his review of those records, as well as his expertise, he opines that the cause of Plaintiff's injuries is the mesh implants. *Id.* at 18.

In his report, Dr. Rosenzweig explains that the injuries Plaintiff complained of are consistent with those caused by devices that develop the same issues described above. *Id.* He goes on to explain the various other factors he ruled out in reaching this conclusion. Dr. Rosenzweig considered her medical history including her biological grafts; smoking history; the standard of care by her treating physician; her diabetes; and prior cystoscopies. *Id.* at 18-20. Based on Dr. Rosenzweig's consideration of other likely causes for her pain, the Court finds that his differential diagnosis properly ruled those out.

Because the Court finds Dr. Rosenzweig's differential diagnosis fits the reliability standard, the Court **DENIES** Ethicon's motion on this point. Ethicon is free to cross-examine Dr. Rosenzweig on his diagnosis. But Dr. Rosenzweig is not "simply guessing," as Ethicon suggests. He has conducted a reliable differential diagnosis; and any alleged errors are matters of weight, not admissibility. *Tyree*, 54 F. Supp. 3d at 566 (citing *Westberry*, 178 F.3d at 265).

vii. Testimony regarding Plaintiff's long-term prognosis

Dr. Rosenzweig's report states that, in his opinion, Plaintiff will continue to have ongoing complications, and may need additional procedures to remove any remaining mesh or vaginal surgeries to treat scarring, pain, and recurrent infections. Plaintiff will also likely require pelvic floor therapy and physical therapy. (Doc. 44-2 at 21-22). Ethicon challenges these opinions as speculative because Dr. Rosenzweig never examined Plaintiff, does not cite to treating physician's records finding Plaintiff has a permanent injury, and gives no support for his opinions about future

care. Plaintiffs respond that his opinions are based upon his extensive knowledge, training, and experience, as well as his review of her medical records.

The cases in the Ethicon MDL abound with recitations of Dr. Rosenzweig's qualifications. A couple of recent examples, which also discuss prognoses, are cited below. As other courts have discussed *ad nauseum*, Dr. Rosenzweig is a urogynecologist who has performed over a thousand pelvic floor surgeries including over 350 dealing with mesh complications. He is quite familiar with pelvic mesh implants, including Ethicon's, and is well-versed in the literature.

Dr. Rosenzweig's prognosis is sufficiently grounded in his expertise, and the fact that he did not physically examine her does not preclude that finding. As other courts have found, "Defendants' challenge is to Dr. Rosenzweig's conclusions, not his methodology." *Tucker v. Ethicon, Inc.*, No. 4:20-CV-1543 RLW, 2021 WL 825921, at *7 (E.D. Mo. Mar. 4, 2021); *see also Williams v. Ethicon, Inc.*, No. 1:20-CV-04341-SDG, 2021 WL 857747, at *7 (N.D. Ga. Mar. 8, 2021) (noting that "other courts have rejected this precise argument"), *Hosbrook v. Ethicon, Inc.*, No. 3:20-CV-88, 2020 WL 5214644, at *5 (S.D. Ohio Sept. 1, 2020). Ethicon is free to cross-examine Dr. Rosenzweig on his conclusions, but the Court will not exclude them. Ethicon's Motion is **DENIED** on this point.

IV. CONCLUSION

The Court **DENIES** Ethicon' Motion for Partial Summary Judgment as to Plaintiffs' failure to warn claim (Count III) and **GRANTS** the motion as to Plaintiffs' NIED claim (Count X). The Court further **GRANTS IN PART** and **DENIES IN PART** Ethicon's *Daubert* Motion for Dr. Rosenzweig, as discussed above.

IT IS SO ORDERED.

SIGNED at Houston, Texas on this the 23rd day of March, 2021.

KEITH P. ELLISON
UNITED STATES DISTRICT JUDGE